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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,337	07/26/2001	Satoshi Mori	55107	5232

21874 7590 06/15/2005

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EXAMINER
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FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/674,337	MORI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 27-36 is/are pending in the application.
- 4a) Of the above claim(s) 8-26 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 3 and 27-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 05/18/2005 has been entered.
2. Claims 1, 3 and 27-36 are under consideration in this Office Action.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 3, 27-30, and 31-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nicotianamine synthase comprising an amino acid sequence of SEQ ID NO: 1; does not reasonably provide enablement for an enzyme comprising an amino acid sequence that has at least 50%, 90%, or 95% amino acid sequence identity to SEQ ID NO: 1 comprising any of the consensus amino acid sequences depicted in said claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicants' arguments filed 05/18/2005 have been fully considered but they are not persuasive. Applicants' position is that the claims as amended requires activity of more than 25% of the nicotianamine synthase activity of SEQ ID NO: 1, and that there is not only a sequence identity requirement but also an activity requirement including an assay for measuring activity. Applicants argue that one of skill in the art need not be taught which amino acid residue(s) can be changed without inactivating enzyme activity and that certain amino acids are conserved between nicotianamine synthases as shown in Figure 7 of the specification and the alignment attached to the amendment filed 05/18/2005. Applicants note that the sequence identity of SEQ ID NO: 1 to

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four other barley sequences are 61%-73% while that of one non-barely sequence is 75%. The Examiner respectfully disagrees for the reasons of record as supplemented below.

As stated in the previous Office Action the standard for meeting the enablement requirement is whether one of skill in the art can make the invention without undue experimentation. However, the limitations that the claimed nicotianamine synthase variants must have activity of more than 25% of the nicotianamine synthase activity of SEQ ID NO: 1 and that the activity is measured by an assay does not enable one of skill in the art to make the invention without undue experimentation. These limitations require searching and screening for the invention which is not teaching or guidance for making the invention.

The amount of experimentation to make the nicotianamine synthase having 50%, 90%, and 95% identity to SEQ ID NO: 1 comprising at least one of amino acid sequences SEQ ID Nos: 23-28 recited in claim 27 and having 101 conserved amino acids recited in claim 28 is undue for the reasons stated in the previous Office Action. SEQ ID NO: 1 is disclosed by the specification as an amino acid sequence of 328 amino acid residues. The claims require at least 50% of SEQ ID NO: 1 to be altered, where at least 164 amino acid residues are changed (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1 and 101 amino acids must be conserved. One of ordinary skill in the art would have to make and search for proteins having these changes in the amino acid sequence and then determine by enzymatic assays whether the protein has nicotianamine synthase activity. Limiting the claims to recite the specific amino acid sequences of SEQ ID Nos: 23-28 does not overcome the rejection since no more than 32 amino acid residues are accounted for.

Furthermore, claims 29 and 30 which recites 90% and 95% identity, respectively, to SEQ ID NO: 1 requires making and screening for 33 amino acid residues that can be altered without inactivating enzyme activity. Thus, one of ordinary skill in the art would have to make and search for proteins having these changes in the amino acid sequence and then determine by enzymatic assays whether the protein has nicotianamine synthase activity. Such making and searching is outside the scope of routine experimentation.

The amount of experimentation to make the nicotianamine synthase having 50%, 90%, or 95% identity to SEQ ID NO: 1 comprising at least one of amino acid sequences SEQ ID Nos: 23-28 recited in claim 35 and having 101 conserved amino acids recited in claim 36 is undue. The claims require at least 50%, of SEQ ID NO: 1 to be altered, where at least 33 amino acid residues are changed (deletion, insertion, substitution, or combinations thereof) in SEQ ID NO: 1 and 101 amino acids must be conserved. One of ordinary skill in the art would have to make and search for proteins having these changes in the amino acid sequence and then determine by enzymatic assays whether the protein has nicotianamine synthase activity. Limiting the claims to recite the specific amino acid sequences of SEQ ID Nos: 23-28 does not overcome the rejection since no

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more than 32 amino acid residues out of a total of 328 amino acid residues of SEQ ID NO: 1 are accounted for.

For the reasons stated above, the Examiner maintains the position that an undue amount of experimentation would be required to make the invention of claims 3, 27-29, and 31-36.

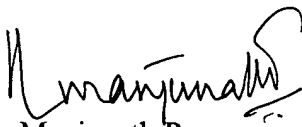
*Conclusion*

5. Claim 1 is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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